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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,073	04/16/2001	Asim Dasgupta	220002054822	5718

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

14

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,073

Applicant(s)

DASGUPTA ET AL.

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-12 in Paper No. 13, filed 3/18/03 is acknowledged.

Claims 13-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

It is noted that in paper No. 5, filed 2/22/02 applicant has requested correction of the filing receipt to include priority to application No. 09/316,630. It is noted, however that applicant has not claimed priority to that application.

Applicants filing papers and all further submitted papers do not provide for a claim of priority to 09/316,630.

The instant application is granted an effective filing date of 4/16/01.

See paper No. 6 mailed 3/27/02.

The information disclosure statement filed 2/1/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each

publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claims 1-5 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "wherein all amino acids are gene encoded". This language is unclear since amino acids are "encoded" by codons and not genes. It is unclear what limitations are intended with this language, for example.

Claims 3-5 all recite the limitation "Aⁱ". There is no antecedent basis for this limitation in the claims. "Aⁱ" has not been defined in the claims, for example. Claim 3 refers to "Aⁱ subunits" which is further removed from the formula of Claim 1, for example.

Claim 11 claims SEQ ID NO: 16. SEQ ID NO: 16 is 19 amino acids long. The formula of claim 1 requires the peptides be 15-18 amino acids in length. Since the claimed species does not fit within the formula of claim 1, it is unclear what the formula of claim 1 requires and/or what is claimed in claim 11, for example.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,291,637. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and those of 6,291,637 both specifically and generically claim compounds and compositions that include LAP of the La auto antigen. The formulae of the instant claim 1 clearly embraces the LAP sequence of the 6,291,637 and further SEQ ID NO: 16 of the instant application is the same as LAP, for example. The subject matter claimed in both the instant application clearly embrace and further specifically claim the same compounds.

Claims 1-9, 11 and 12 are directed to the same invention as that of claims 1-5 of commonly assigned 6,291,637. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership

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(see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 includes a peptide defined by SEQ ID NO 16 which is 19 amino acids long. Formula (1) requires the claimed compound be 15-18 amino acids in length.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 5-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Das et al [WO 99/61613].

Das et al have disclosed a peptide LAP that complies with the formula of instant claim 1, is the same as instant SEQ ID NO: 14. The amino acid sequence [LAP] is encoded within the La autoantigen, for example. LAP has the required substituents at A⁴, A¹², A¹⁷, A¹³, A¹⁴, A¹⁵, A⁸, A⁶, A⁹, and A¹⁰ as recited in instant claims 6-9. Claim 6 of Das et al discloses an antiviral composition comprising the LAP peptide and a pharmaceutical carrier.

It is noted that at paragraph 23 of the instant specification it is asserted that the "LAP" peptide (SEQ ID NO: 1) is excluded by the formula (1). It appears that LAP falls squarely into formula (1). It is noted that the dependent claims 6-9 define species that also embrace LAP. Furthermore SEQ ID NO: 14 the "bovine" sequence listed in Table 1 is the exact sequence of LAP (SEQ ID NO: 1) in Table 1. On one hand the specification asserts that LAP is not included and on the other the LAP sequence is specifically claimed in Claim 11, for example. The invention has been interpreted to include LAP within the scope of formula (1) since the formula specifically embraces LAP as evidenced by the claiming of SEQ ID NO:14, for example.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides of formula (1) that comprise E at A⁴, A at A⁶, I at A⁷, C at A⁸, Q at A¹⁰, I at A¹¹, E at A¹², Y at A¹³, F at A¹⁵, G at A¹⁶, D at A¹⁷, F at A¹⁸ does not reasonably provide enablement for the full scope of formula (1). The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant invention is drawn to the use of peptides based on LAP which inhibit viral replication. The instant claim are broadly drawn to peptides embraced within formula (1) and also includes specific peptides in claims 11 and 10, for example.

Applicant has shown in Table 1, that peptides based on LAP that comprises E at A⁴, A at A⁶, I at A⁷, C at A⁸, Q at A¹⁰, I at A¹¹, E at A¹², Y at A¹³, F at A¹⁵, G at A¹⁶, D at A¹⁷, F at A¹⁸ function to inhibit viral replication. Table 1 show that those that do not comprise these specific amino acid residues at these position do not work as viral inhibitors.

Table I shows that the specifically claimed SEQ ID NO: 3 (701) did not have viral inhibitory properties. It does not appear based on applicants disclosure that one in the art would expect that peptide that are embraced within the broad formula (1) would be expected to have antiviral properties since it has been shown that only those with E at A⁴, A at A⁶, I at A⁷, C at A⁸, Q at A¹⁰, I at A¹¹, E at A¹², Y at A¹³, F at A¹⁵, G at A¹⁶, D at A¹⁷, F at A¹⁸ show inhibitory properties. The specification does not provide any other use for the peptides within formula (1) other than as viral inhibitors. One in the art therefore would not know what to use those peptides embraced within formula (1) that do not have inhibitory properties, for example. One in the art would not know how to use 701, for example. Claim 11 comprises specific sequences that do not contain E at A⁴, A at A⁶, I at A⁷, C at A⁸, Q at A¹⁰, I at A¹¹, E at A¹², Y at A¹³, F at A¹⁵, G at A¹⁶, D at A¹⁷, F at A¹⁸ and based on the instant specification (Table 1) and would therefore not be

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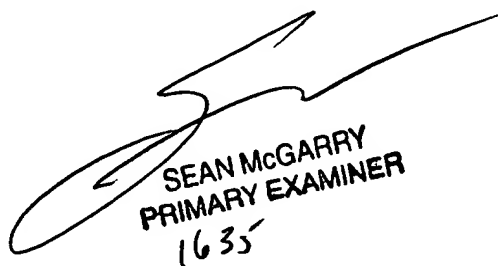
expected to have those antiviral properties associated with LAP, for example. The structure of Formula (1) has not been demonstrated to correlate with the asserted activity of viral inhibition. One in the art would be required to perform undue experimentation to practice the instant invention since one would be required to perform undue trial and error experimentation to determine what particular uses those species within formula (1) have that do not possess antiviral properties, for example.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM
May 28, 2003


SEAN MCGARRY
PRIMARY EXAMINER
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